IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

KIM GOODLING and
NORMAN GOODLING, SR.,

Plaintiffs,

v.

JOHNSON & JOHNSON and
ETHICON, INC.,

Defendants.

No. 4:21-CV-00082

(Chief Judge Brann)

MEMORANDUM OPINION

FEBRUARY 10, 2022

Plaintiffs Kim and Norman Goodling bring this fourteen-count suit against Johnson & Johnson and its wholly-owned subsidiary Ethicon, Inc., seeking damages for injuries they allegedly suffered after Ms. Goodling was implanted with the Defendants' pelvic mesh product. This is one of many suits filed across the country by women implanted with this medical device. The Defendants move to dismiss the Goodlings' Amended Complaint, raising particular issue with the lack of case-specific allegations—indeed, many (if not most) of the 358 paragraphs in the Amended Complaint appear to be copied verbatim from other complaints filed by other plaintiffs. Although the Court finds the allegations insufficient to sustain certain claims, others will be allowed to proceed. For the reasons provided below, the Defendants' motion to dismiss is granted in part, denied in part.

I. BACKGROUND

On December 5, 2011, Kim Goodling went to the Milton S. Hershey Medical Center in Hershey, Pennsylvania for a surgical procedure to treat stress urinary incontinence.[1] Specifically, her physician, Dr. Matthew Davies, implanted in her a Gynecare TVT-Exact pelvic mesh product ("TVT device" or "pelvic mesh product") designed and manufactured by Defendant Ethicon, Inc., a wholly-owned subsidiary of Defendant Johnson & Johnson.[2]

Prior to the implantation procedure, Ms. Goodling met with her medical providers, including Dr. Davies, to discuss possible treatments for the mild stress urinary incontinence she was experiencing.[3] At that time, the Defendants "made assurances" to Dr. Davies and other health care professionals that their TVT device "was safe and reasonably fit" to address health concerns like Ms. Goodling's.[4] The Defendants represented that the TVT device is a "permanent implant" that would "permanently cure or alleviate" stress urinary continence—the pelvic mesh product would not "contract," "shrink," or "degrade," and as such, "would not need to be partially removed."[5] Relying on these commitments—which the Defendants made in their "instructions for use" for the TVT device as well as in pamphlets, commercial documents, and other oral and written statements—Dr. Davies

1 Doc. 13 ¶¶ 2, 217.
2 *Id.* ¶¶ 2, 12, 30.
3 *Id.* ¶¶ 5, 81.
4 *Id.* ¶ 198.
5 *Id.* ¶¶ 197, 207.

recommended the pelvic mesh product as a treatment option.[6] Ms. Goodling consented to the implantation procedure.[7]

Unbeknownst to either Ms. Goodling or Dr. Davies, the TVT device "has high rates of failure, injury, and complications, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damages to a significant number of women."[8] Specifically, after implantation, the TVT device often "contracts, shrinks, frays, cords, curls, migrates, stiffens, loses pore size with tension, and/or otherwise degrades."[9] These complications are attributable to defects in the pelvic mesh product's design—in particular, the use of "polypropylene," a type of plastic that is "biologically incompatible with human tissue":

> [P]olypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's TVT [device]. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response, and chronic pain. It also can cause new-onset painful sexual relations, significant dysfunction, vaginal shortening and anatomic

---

6 *Id.* ¶¶ 152, 158.
7 *Id.* ¶ 158.
8 *Id.* ¶ 65.
9 *Id.* ¶ 147.

> deformation, and can contribute to the formation of severe adverse reactions to the mesh.[10]

Further, the TVT device contains "collagen," which causes "adverse tissue reactions" that are "causally related to infection, as the collagen is a foreign organic material."[11] Other potential design defects include "[t]he use of laser-cut or mechanical cut polypropylene mesh," which "contributed to the sharp edges of the [TVT] device," and the failure to use a "sheath" for insertion, which "can lead to mesh erosions."[12]

The Defendants "were and are aware that their TVT [device]" causes these complications; however, they "failed to disclose and misrepresented" these risks to Ms. Goodling's "implanting physician."[13] Specifically, the "Instructions for Use ('IFU') and pamphlets or commercial documents for the TVT [device]" that the Defendants provided to implanting physicians, including Dr. Davies, "fail[ed] to detail the extent and frequency of known complications, including mesh erosion and extrusion."[14] If Dr. Davies knew of the risks associated with the Defendants' pelvic mesh product, he "would have conveyed [this] information to [Ms. Goodling] during her consent process."[15] And had she been "informed of all known relevant risks," Ms. Goodling "would not have consented to having the

---

[10] *Id.* ¶¶ 3, 21–22.
[11] *Id.* ¶ 23.
[12] *Id.* ¶¶ 134–35.
[13] *Id.* ¶¶ 63, 147.
[14] *Id.* ¶¶ 152, 157.
[15] *Id.* ¶ 158.

TVT device implanted in her" and her "implanting physician would not have implanted the TVT device."[16]

After the implantation procedure, Ms. Goodling "developed complications arising from the implant."[17] Specifically, the mild stress urinary incontinence that she experienced prior to the procedure "significantly increased in frequency after mesh implantation," and she also suffered "onset pelvic pain, vaginal bleeding, urinary tract infections, dyspareunia, vaginal scarring, urinary urgency, [and] voiding dysfunction."[18] According to the Goodlings, these complications "were all caused by the defective propensities of the TVT [device]."[19]

The Goodlings initiated this lawsuit on January 14, 2021.[20] Four months later, on May 19, 2021, the Goodlings filed an Amended Complaint, which included fourteen counts sounding in strict liability, negligence, fraud, breach of warranty, unjust enrichment, loss of consortium, and punitive damages.[21] The Defendants moved to dismiss the Amended Complaint on June 9, 2021.[22] That motion has been fully briefed and is now ripe for disposition.[23]

---

16 *Id.*
17 *Id.* ¶ 4.
18 *Id.* ¶ 5.
19 *Id.*
20 Doc. 1.
21 Doc. 13.
22 Doc. 16.
23 *See* Doc. 17; Doc. 18; Doc. 19.

II. LAW

Under Federal Rule of Civil Procedure 12(b)(6), the Court dismisses a complaint, in whole or in part, if the plaintiff fails to "state a claim upon which relief can be granted." Following the landmark decisions of *Bell Atlantic Corp. v. Twombly*[24] and *Ashcroft v. Iqbal*,[25] "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'"[26] The United States Court of Appeals for the Third Circuit has instructed that "[u]nder the pleading regime established by *Twombly* and *Iqbal*, a court reviewing the sufficiency of a complaint must take three steps": (1) "take note of the elements the plaintiff must plead to state a claim"; (2) "identify allegations that, because they are no more than conclusions, are not entitled to the assumption of truth"; and (3) "assume the[] veracity" of all "well-pleaded factual allegations" and then "determine whether they plausibly give rise to an entitlement to relief."[27]

III. ANALYSIS

A. Shotgun Pleading

As a preliminary matter, the Defendants argue that the Amended Complaint is an impermissible "shotgun pleading," as it "is virtually identical to numerous

---

[24] 550 U.S. 544 (2007).
[25] 556 U.S. 662 (2009).
[26] *Id.* at 678 (quoting *Twombly*, 550 U.S. at 570).
[27] *Connelly v. Lane Construction Corp.*, 809 F.3d 780, 787 (3d Cir. 2016) (internal quotations and citations omitted).

other amended complaints that have been filed around the country" and "does not include sufficient case-specific facts to state a claim."[28] The "unifying characteristic" of shotgun pleadings "is that they fail to one degree or another, and in one way or another, to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests."[29] Upon review, the Court finds that although the Amended Complaint primarily focuses on the Defendants' pelvic mesh product—and provides comparatively little information about Ms. Goodling's procedure and injuries—it nevertheless gives the Defendants adequate notice of the claims and supporting facts, and, therefore, cannot be characterized as a shotgun pleading.[30]

B. Strict Liability (Counts II–IV)

Next, the Defendants ask the Court to dismiss the Goodlings' strict liability claims[31] because "Pennsylvania does not recognize strict liability claims arising

---

[28] Doc. 17 at 7–9.

[29] *Drumheller v. Johnson & Johnson*, 2021 WL 1853407, at *5 (E.D. Pa. May 10, 2021) (citation and internal quotation marks omitted).

[30] *See id.* at 5–6 (complaint alleging harm associated with pelvic mesh product, which "largely focused on Ethicon on a macro level rather than the discovery and treatment of specific harm, does not fall into any of the[] four categories" of shotgun pleadings); *Baca v. Johnson & Johnson*, 2020 WL 6450294, at *1 –2 (D. Ariz. Nov. 2, 2020) (case "alleg[ing] defects in pelvic repair systems developed by Defendants Johnson & Johnson and Ethicon, Inc." that contains only "three allegations . . . that appear tailored to [the] Plaintiff"—the "remaining 244 allegations can be found, word-for-word, in other complaints filed in various federal courts"—"adequately gives notice" and thus "cannot be characterized as a shotgun pleading").

[31] The Goodlings allege three separate strict liability claims premised on distinct theories of liability: design defect (Count II); manufacturing defect (Count III); and failure to warn (Count IV).

from the use of prescription medical products."[32] According to the Defendants, "[t]he majority of Pennsylvania federal district courts directly confronting the issue have followed [*Creazzo v. Medtronic, Inc.*] in dismissing strict liability claims against medical device manufacturers."[33] The Goodlings dispute this, citing numerous decisions by district judges in this Circuit (including several from within this District) permitting strict liability claims against medical device manufacturers.[34]

As demonstrated by the parties' competing citations, federal district courts in Pennsylvania differ on this question, though opinions have become relatively well-established. Indeed, this is now the third time in two years I have confronted this issue.[35] As I noted in my prior opinions, I find the Honorable Gerald J. Pappert's reasoning in *Ebert v. C.R. Bard, Inc.*[36] persuasive, and again adopt it here.

---

[32] Doc. 17 at 3 (citing *Hahn v. Richter*, 673 A.2d 888, 889–90 (Pa. 1996); *Creazzo v. Medtronic, Inc.*, 903 A.2d 24 (Pa. Super. 2006)).

[33] *Id*. (citing *Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572, 577–78 (E.D. Pa. 2019); *Buck v. Endo Pharmaceuticals, Inc.*, 2019 WL 1900475, at *1 (E.D. Pa. Apr. 29, 2019); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 833 (E.D. Pa. 2016); *Wilson v. Synthes USA Products, LLC*, 116 F. Supp. 3d 463, 465–66 (E.D. Pa. 2015); *Cogswell v. Wright Medical Tech., Inc.*, 2015 WL 4393385, at *2 (W.D. Pa. July 16, 2015).

[34] Doc. 18 at 3–4 (citing *Smith v. Howmedica Osteonics Corp.*, 251 F. Supp. 3d 844, 847 (E.D. Pa. 2017); *Russell v. Ethicon, Inc.*, 2020 WL 5993774, at *7 (M.D. Pa. Oct. 9, 2020); *Patchcoski v. W.L. Gore & Associates, Inc.*, 2020 WL 4335016, at *7–8 (M.D. Pa. July 28, 2020) (Mannion, J.)).

[35] *See Russell*, 2020 WL 5993774, at *7; *Lavore v. Boston Scientific Corp.*, 2020 WL 3469061, at *3–4 (M.D. Pa. June 25, 2020).

[36] 459 F. Supp. 3d 637, 651–53 (E.D. Pa. 2020).

In short, the Pennsylvania Superior Court ruled in its 2006 decision *Creazzo v. Medtronic, Inc.* that under comment k of the Second (Restatement) of Torts § 402A—which "excludes certain products from the definition of 'unreasonably dangerous' . . . on the basis that they are incapable of being made safe for their intended use, but are useful nonetheless"—strict liability cannot be a basis for liability in cases involving medical devices.[37] But this decision, which district courts often rely on to predict a categorical ban, is "supported by scant reasoning," and in the sixteen years since it was issued, "the Pennsylvania Supreme Court has not relied on it."[38] This makes *Creazzo*, in this Court's eyes, not particularly persuasive. Moreover, two 2014 Pennsylvania Supreme Court decisions,[39] "taken together, undermine *Creazzo*'s persuasive force and suggest that the Pennsylvania Supreme Court would not apply comment k to categorically exempt all prescription medical devices from strict liability claims."[40]

Accordingly, this Court "predicts that the Pennsylvania Supreme Court would not categorically [bar strict liability claims against] all prescription medical device manufacturers," and "would instead analyze comment k's applicability to prescription medical devices on a case-by-case basis, determined largely by each

---

37 903 A.2d at 30–31.
38 *Ebert*, 459 F. Supp. 3d at 652.
39 *See Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 396 (Pa. 2014); *Lance v. Wyeth*, 85 A.3d 434, 454 (Pa. 2014).
40 *Ebert*, 459 F. Supp. 3d at 652.

case's developed factual record and the individual characteristics of the medical device at issue."[41]

Here, based on the allegations in the Amended Complaint, the Court cannot conclude that the mesh product implanted in Ms. Goodling is an "unavoidably unsafe product" that is shielded from strict liability under Pennsylvania law. The Defendants merely invoke comment k without providing any argument as to why its product is immune from liability. As such, the Defendants have failed to establish that "in the present state of human knowledge," their pelvic mesh product was "quite incapable of being made safe for [its] intended and ordinary use."[42] The Defendants' motion to dismiss the Goodlings' strict liability claims on this basis is therefore denied.

C. Negligence Claims (Counts I–IV, IX, X)

The Defendants next challenge the sufficiency of the pleadings underlying the Goodlings' five negligence-based causes of action: (a) design defect,[43] (b) manufacturing defect,[44] (c) failure to warn,[45] (d) negligent misrepresentation,[46] and (e) negligent infliction of emotional distress.[47] The Court addresses each negligence-based theory of liability in turn.

---

41 *Id*. at 652–53.
42 Restatement (Second) of Torts, § 402A, comment k.
43 Counts I and II. *See* Doc. 13 ¶¶ 91–92, 112–25.
44 Count III. *See* Doc. 13 ¶¶ 126–38.
45 Counts I and IV. *See* Doc. 13 ¶¶ 98, 139–71.
46 Count IX. *See* Doc. 13 ¶¶ 241–74.
47 Count X. *See* Doc. 13 ¶¶ 275–86.

1. Design Defect (Counts I and II)

The Defendants argue that the Amended Complaint does not contain "sufficient facts that would plausibly show a design defect or causation."[48] Specifically, the Defendants assert that "[o]ther than criticizing the products for containing polypropylene, the [Amended Complaint] states very little about how the design of the product was flawed."[49] Additionally, the Defendants contend that the Goodlings "plead no facts that would show that their injuries are plausibly the result of a design defect with the [TVT device] rather than an injury consistent with any stress urinary incontinence surgery."[50] The Goodlings respond that the Amended Complaint "is replete with allegations identifying the precise nature of the TVT [device's] design, manufacturing, and warning defects pertaining to the specific pelvic mesh implanted in [Ms. Goodling] and how those specific defects caused [her] injuries."[51]

To establish negligent design under Pennsylvania law, a plaintiff "must show that (1) the manufacturer [owed] a duty to the plaintiff, (2) the duty was

---

48 Doc. 17 at 12.

49 *Id*. at 10.

50 *Id*. at 11–12 (noting that "the extent of [the Goodlings'] proximate causation allegation is [a] conclusory sentence borrowed from other plaintiffs' complaints: 'As a direct and proximate result of the TBT [device's] aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.'") (citing Doc. 13 ¶ 124).

51 Doc. 18 at 9 (citing Doc. 13 ¶¶ 2–8, 21–23, 35, 41, 47, 87–111, and 112–25).

breached, and (3) such a breach was the proximate cause of [the] plaintiff's injuries."[52] Under the "design defect theory, plaintiffs must prove that the product is defective and that at the time it left the control of the manufacturer it lacked the feature necessary to make it safe for its intended use, or contained a feature that made it unsafe for its intended use."[53] Consistent with Federal Rule of Civil Procedure 8(a) and the Supreme Court rulings in *Twombly* and *Iqbal*, design defect claims survive motions to dismiss so long as the pleadings put defendants "on notice of the allegations against [them] and of the alleged issues for which [they] may be liable."[54] Courts recognize that "[r]equiring anything more" at the motion to dismiss phase "is impractical given the fact- and discovery-intensive nature of products liability claims."[55]

Here, the Amended Complaint provides that Ms. Goodling was implanted with the Defendants' pelvic mesh product on December 5, 2011, to treat "stress urinary incontinence."[56] After the implantation procedure, Ms. Goodling "developed complications arising from the implant."[57] Specifically, the mild stress urinary incontinence that she experienced prior to the procedure "significantly

---

52 *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 753 (E.D. Pa. 2007) (citing *Phillips v. Cricket Lighters*, 841 A.2d 1000, 1008 (Pa. 2003); *Dauphin Deposit Bank & Trust v. Toyota*, 596 A.2d 845, 849–50 (Pa. Super. 1991)).

53 *Tincher*, 104 A.3d at 339.

54 *Fassett v. Sears Holdings Corp.*, 2015 WL 5093397, at *6 (M.D. Pa. Aug. 18, 2015).

55 *Id.*; *see also Drumheller*, 2021 WL 1853407, at *7 (denying motion to dismiss where plaintiff's "allegations place [defendant] on notice of the negligent design claim").

56 Doc. 13 ¶¶ 2, 217.

57 *Id.* ¶ 4.

increased in frequency," and she also suffered "onset pelvic pain, vaginal bleeding, urinary tract infections, dyspareunia, vaginal scarring, urinary urgency, [and] voiding dysfunction."[58] According to the Goodlings, these complications "were all caused by the defective propensities of the TVT [device]."[59] In particular, the Goodlings explain that "[t]he TVT [device] is made from polypropylene, a type of plastic," that is "biologically incompatible with human tissue."[60] Further, the Goodlings allege that the Defendants' pelvic mesh product contained "collagen," which causes "adverse tissue reactions" that are "causally related to infection, as the collagen is a foreign organic material."[61]

When confronting similar claims supported by similar allegations, federal district courts have reached different conclusions. For example, in *Drumheller v. Johnson & Johnson*, the Honorable Mark A. Kearney of the Eastern District of Pennsylvania was asked to dismiss a negligent design claim nearly identical to the Goodlings'—indeed, the plaintiff, who was represented by the same attorneys as the Goodlings, brought the same claims against the same defendants based on the same allegations of wrongdoing.[62] Judge Kearney denied the defendants' motion to dismiss the negligent design claim, explaining that the plaintiff's "allegations place

---

58 *Id.* ¶ 5.
59 *Id.*
60 *Id.* ¶¶ 3, 21–22.
61 *Id.* ¶ 23.
62 2021 WL 1853407, at *7.

[the defendants] on notice."[63] Specifically, Judge Kearney reasoned that the plaintiff "alleges the specific injuries she suffered—worsening urinary incontinence, intrinsic sphincter deficiency, pelvic pain, dyspareunia—and she identifies how the specific design characteristics of the products—the use of polypropylene and collagen—contributed to these injuries."[64]

Conversely, in *Baca v. Johnson & Johnson*—another case brought against the same defendants regarding negative side effects allegedly associated with the same pelvic mesh product—the Honorable Diane J. Humetewa of the District of Arizona rejected the plaintiff's design defect claims because her allegations did not demonstrate that the alleged defect proximately caused her injuries.[65] Judge Humetewa noted that the plaintiff alleged only that (a) she was implanted with the product, (b) she later had the product surgically removed, (c) other individuals who received the product suffered an adverse immune response, and (d) the product is prone to failure and caused injury to the plaintiff.[66] Because the complaint did not state that the plaintiff suffered from an adverse immune response or otherwise describe how the product implanted in the plaintiff failed, Judge Humetewa concluded that the complaint "simply fail[ed] to show how the Product caused *this* Plaintiff's specific injury."[67]

---

63 *Id.*
64 *Id.*
65 2020 WL 6450294, at *4.
66 *Id.*
67 *Id.*

Similarly, in *Hernandez v. Johnson & Johnson*, the Honorable Salvador Mendoza, Jr. of the Eastern District of Washington dismissed the plaintiff's design defect claim because she "fail[ed] to allege facts about the device's safety or design" and "also fail[ed] to address causation (i.e., how the alleged defects caused her harm)."[68] The plaintiff alleged that the pelvic mesh product "eroded after implantation, causing her to need revision surgery," and asserted that the product "has high failure, injury, and complication rates, fails to perform as intended, requires frequent and often debilitat[ing] re-operations, and has caused severe and irreversible injuries . . . to a significant number of women, including the Plaintiff."[69] According to Judge Mendoza, the plaintiff did not "specifically allege that the design's alleged inability to be safely removed caused her injuries," and similarly did not "plausibly allege the device's *design itself* caused the damages."[70]

Given the similarity of the pleadings here and in *Drumheller*, the Court finds Judge Kearney's analysis most applicable and persuasive. Like the plaintiff in *Drumheller*, the Goodlings allege the specific injuries Ms. Goodling suffered and how the TVT device's design characteristics contributed to these injuries; they do not merely allege that the Defendants' pelvic mesh product is generally prone to failure or vaguely assert that it caused severe and irreversible harm. That level of specificity is sufficient to put the Defendants "on notice of the allegations against

---

68 2021 WL 320612, at *3 (E.D. Wash. Jan. 8, 2021).
69 *Id.*
70 *Id.*

[them] and of the alleged issues for which [they] may be liable," which is all the Goodlings must do to survive dismissal at this stage.[71] Accordingly, the Defendants' motion to dismiss the Goodlings' design defect claims (Counts I and II) is denied.

2. Manufacturing Defect (Count III)

The Defendants similarly argue that the pleadings do not support a manufacturing defect claim, asserting that the Goodlings "fail to plead how the [pelvic] mesh product deviated from its intended design" and do not "allege facts that would plausibly show how any unidentified error in the fabrication process caused her claimed injuries."[72] In response, the Goodlings highlight two allegations that purportedly show manufacturing defect: (1) "the process by which the TVT [device] was cut, either by laser or mechanically, created unintended sharp edges of the device, which caused [Ms. Goodling's] injuries";[73] and (2) "the TVT [device] deviated in design because it did not contain a sheath."[74] But, on this, the Court agrees with the Defendants.[75]

To prove a manufacturing defect claim, a plaintiff must show that the product at issue "deviat[ed] from [the] product's intended design."[76] Courts

---

71 *Fassett*, 2015 WL 5093397, at *6; *see also Drumheller*, 2021 WL 1853407, at *7.
72 Doc. 17 at 13, 15.
73 Doc. 18 at 11 (citing Doc. 13 ¶¶ 134, 136).
74 *Id*. (citing Doc. 13 ¶ 135).
75 Doc. 17 at 14 (arguing that the Goodlings do not "allege facts suggesting that the mesh in the specific TVT Exact implanted in [Ms. Goodling] was cut differently than the mesh in any other Gynecare TVT Exact or that the cutting of the mesh deviated from specifications").
76 *Chandler v. L'Oreal USA, Inc.*, 774 F. App'x 752, 754 (3d Cir. 2019).

recognize that "[g]enerally, a manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line."[77]

In *Drumheller*, Judge Kearney dismissed the plaintiff's negligent manufacturing claim because "the gravamen of [the plaintiff's] complaint is defect in the design of pelvic mesh."[78] There, the plaintiff similarly argued that "the way [the Defendants] cut the polypropylene mesh either mechanically or by laser created problems upon implant."[79] Judge Kearney found that this allegation "goes to the design of the product," as the plaintiff did not allege "the laser or mechanical cut was unique to the specific product implanted in her"; instead, she alleged that "pelvic mesh products are generally made this way, negatively affecting her and all other patients implanted with pelvic mesh."[80]

Judge Kearney's analysis applies with equal force to the Goodlings' Amended Complaint. Like the plaintiff in *Drumheller*, the Goodlings allege generally that "[t]he use of laser-cut or mechanical cut polypropylene mesh in [the] Defendants' manufacturing process for the TVT [device] contributed to the sharp edges of the device"; they do not plead that the laser or mechanical cut was unique to the specific product implanted in Ms. Goodling or otherwise deviated from the

---

77 *Drumheller*, 2021 WL 1853407, at *8.
78 *Id*. at *7.
79 *Id*. at *8.
80 *Id*.

manufacturing process used for all pelvic mesh products manufactured according to this design.[81] Likewise, the Goodlings allege that "[t]he TVT [device] without a sheath has an abrasive insertion and can lead to mesh erosions," but they make no representations about whether the Defendants' pelvic mesh product, as designed, was supposed to include a sheath.[82]

Because the Goodlings fail to allege facts showing that the pelvic mesh product implanted in Ms. Goodling deviated from a suitable design, they fail to state a claim for negligent manufacturing.[83] Count III is therefore dismissed.[84]

3. Failure to Warn (Counts I and IV)

In their opposition to the Goodlings' negligence claims based on a failure to warn, the Defendants reiterate their objections to the Goodlings' "boilerplate" pleadings, which they argue fail to establish "the essential element of proximate causation."[85] Specifically, the Defendants assert that the Goodlings "fail to identify rudimentary case-specific information, such as the medical condition(s) for which the medical devices were implanted and any specific facts related to her alleged

---

81 Doc. 13 ¶ 134.

82 *Id*. ¶ 135.

83 *See Drumheller*, 2021 WL 1853407, at *8 (dismissing negligent manufacturing claim because plaintiff failed to allege deviation from intended design); *Giacalone v. Lacrimedics, Inc.*, 2008 WL 11365183, at *3 (E.D. Pa. Nov. 24, 2008) (granting summary judgment on strict products liability manufacturing defect because plaintiff "introduced no evidence that [the defendant's products] used by [the plaintiff] differed from any other [of such product] produced by Defendants").

84 This ruling applies equally to the Goodlings' negligence and strict liability claims based on manufacturing defect, as both require a showing that the product deviated from its intended, suitable design.

85 Doc. 17 at 8.

injuries, including the dates that her injuries manifested and other medical treatments."[86] The Goodlings respond that the "allegations in their [Amended Complaint] adequately put [the] Defendants on notice of [the Goodlings'] claims that are based on the [pelvic mesh] product implanted in [Ms. Goodling] which caused her injuries."[87] The Court agrees with the Goodlings.

To maintain a negligence cause of action for failure to warn, a plaintiff must show (1) the defendant owed the plaintiff a duty to warn of certain risks, (2) the defendant breached that duty by failing to warn the plaintiff, and (3) the plaintiff's injuries were proximately caused by the defendant's failure to warn.[88] In cases involving the failure to warn of risks associated with both prescription drugs and medical devices, Pennsylvania applies the learned intermediary doctrine.[89] Under this doctrine, "a manufacturer will be held liable only where it fails to exercise reasonable care to inform a physician of facts which make the [medical device] likely to be dangerous."[90] As such, in an action against a medical device manufacturer based on inadequate warnings, "the issue to be determined is whether

---

86 *Id*. at 9.
87 Doc. 18 at 8.
88 *Cochran v. Wyeth, Inc.*, 3 A.3d 673, 676 (Pa. Super. 2010).
89 *Drumheller*, 2021 WL 1853407, at *9 (citing *Cochran*, 3 A.3d at 676); *see also Runner v. C.R. Bard*, 108 F. Supp. 3d 261, 271–72 (E.D. Pa. 2015) (applying learned intermediary doctrine to failure to warn claim regarding surgical mesh).
90 *Cochran*, 3 A.3d at 676.

the warning, if any, that was given to the prescribing physicians was proper and adequate."[91]

Additionally, Pennsylvania courts emphasize that "[p]roximate cause is an essential element in a failure to warn case."[92] Proximate cause is defined as "a substantial contributing factor in bringing about the harm in question."[93] Therefore, to establish proximate causation, the Goodlings must "show[] that had [the Defendants] issued a proper warning to the learned intermediary," Ms. Goodling "would have altered [her] behavior and the injury would have been avoided."[94]

Here, the Goodlings plead that "[the] Defendants were and are aware that their TVT [device] . . . contracts, shrinks, frays, cords, curls, migrates, stiffens, loses pore size with tension, and/or otherwise degrades" but that they nevertheless "failed to disclose and misrepresented these risks" to Ms. Goodling's "implanting physician."[95] Specifically, the Amended Complaint provides that the Defendants gave Ms. Goodling's implanting physician "Instructions for Use ('IFU') and pamphlets or commercial documents for the TVT [device]" that "fail[ed] to detail the extent and frequency of known complications, including mesh erosion and

---

91 *Taurino v. Ellen*, 579 A.2d 925, 927 (Pa. Super. 1990), *appeal denied*, 589 A.2d 693 (Pa. 1991).

92 *Cochran*, 3 A.3d at 676; *see also Maya v. Johnson and Johnson*, 97 A.3d 1203, 1213 (Pa. Super. 2014) (same).

93 *Cochran*, 3 A.3d at 676 (citing *Whitner v. Von Hintz*, 263 A.2d 889, 893–94 (Pa. 1970)).

94 *Id*.

95 Doc. 13 ¶ 147.

extrusion."[96] According to the Goodlings, the implanting physician "relied on written and/or oral information [he] received from [the] Defendants" and "would have conveyed [this] information to [Ms. Goodling] during her consent process."[97] The Goodlings allege that "if she was informed of all known relevant risks," Ms. Goodling "would not have consented to having the TVT device implanted insider her" and her "implanting physician would not have implanted the TVT device."[98]

The Court finds these allegations "sufficient at this early stage of litigation to state a claim for negligent failure to warn."[99] The Defendants' motion to dismiss Count IV (as well as Count I, to the extent it is predicated on the Defendants' failure to warn) is denied.

4. Negligent Misrepresentation (Count IX)

The Defendants next argue that the Goodlings' negligent misrepresentation claim "is premised on the notion that [they] failed to disclose material information about the [pelvic] mesh products' safety," and as such, it "should be dismissed because, under Pennsylvania law, 'negligence for failure to warn is the sole theory under which a plaintiff can recover against a prescription drug manufacturer when the claim is essentially that the drug company knew of dangers associated with the product but concealed that information while fraudulently misrepresenting the

96 *Id*. ¶¶ 152, 157.
97 *Id*. ¶ 158.
98 *Id*.
99 *Drumheller*, 2021 WL 1853407, at *9.

product's safety.'"[100] The Court agrees with the Defendants. In the Amended Complaint, the Goodlings make no effort to differentiate their failure to warn and negligent misrepresentation claims, repeating (oftentimes verbatim) the same allegations for both counts.[101] Because the Goodlings' negligent misrepresentation claim "sound[s] in failure-to-warn" and the "sole avenue for recovery for these types of claims is negligent failure to warn," the Court dismisses this claim (Count IX) with prejudice.[102]

5. Negligent Infliction of Emotional Distress (Count X)

The Defendants contend that the Goodlings' final negligence-based claim—negligent infliction of emotional distress—is "based on the same three theories on which their strict liability [and other negligence claims] are based," and, as such, is deficient "for the same reasons."[103] But that's not true.

---

[100] Doc. 17 at 17 (quoting *Drumheller*, 2021 WL 1853407, at *16); *see also Runner*, 108 F. Supp. 3d at 268 (same).

[101] *See* Doc. 13, Count IX (Negligent Misrepresentation) ¶¶ 248 ("Defendants breached their duty in representing that Defendants' TVT [device] has no serious side effects . . . ."), 249 (Defendants "knowingly misrepresented to [Ms. Goodling] and her physicians that the TVT [device] is suitable for its intended applications . . . ."), 257 ("Despite this knowledge [of the pelvic mesh product's risks], Defendants continued to market and sell their TVT [device] and procedures as being safe and efficacious . . . ."), 258 ("At all times mentioned herein, Defendants . . . had the duty and obligation to disclose to [Ms. Goodling] and to her physicians, the true facts concerning the aforesaid TVT [device] . . . ."), 259 ("Defendants were under a duty to [Ms. Goodling] to disclose and warn of the defective nature of the TVT [device] . . . ."), 264 ("To this day, Defendants continue to intentionally conceal and/or fail to disclose the true defective nature of their TVT [device], as indicated above."), 265 ("Defendants' failure to disclose this information was a substantial factor in [Ms. Goodling's] physician[']s selecting Defendants' TVT [device] . . . .").

[102] *Drumheller*, 2021 WL 1853407, at *16.

[103] Doc. 17 at 16–17.

As the Goodlings assert, negligence infliction of emotional distress is a distinct cause of action "cognizable under Pennsylvania law."[104] Specifically, Pennsylvania courts recognize causes of action for negligent infliction of emotional distress in "four factual scenarios: (1) situations where the defendant had a contractual or fiduciary duty toward the plaintiff; (2) the plaintiff was subjected to a physical impact; (3) the plaintiff was in a zone of danger, thereby reasonably experiencing a fear of impending physical injury; [and] (4) the plaintiff observed a tortious injury to a close relative."[105] When proceeding under the first "theory of recovery, a plaintiff must establish the elements of a negligence claim."[106] Further, it is well established that "[p]hysical injury must be averred to sustain a cause of action for negligent infliction of emotional distress."[107]

Here, the Goodlings allege that the Defendants owed Ms. Goodling, a medical patient implanted with their pelvic mesh product, a duty of care, and that "'physical impact' occurred during the implant of the TVT [device]."[108] Specifically, the Goodlings note that "physical harm occurred after the TVT [device] was implanted since its complications caused [Ms. Goodling's] injuries and continue to do so; and long-standing emotional disturbance as a result of the

---

[104] Doc. 18 at 12 (citing *Runner*, 108 F. Supp. 3d at 272).
[105] *Toney v. Chester County Hospital*, 961 A.2d 192, 197–98 (Pa. Super. 2008), *affirmed*, 36 A.3d 83 (Pa. 2011).
[106] *Id*. at 198.
[107] *Armstrong v. Paoli Memorial Hospital*, 633 A.2d 605, 609 (Pa. 1993).
[108] Doc. 18 at 12.

complications of the [pelvic mesh] product."[109] The Court finds these allegations sufficient at this stage to state a claim for negligent infliction of emotional distress.[110]

D. Fraud-Based Claims (Counts V, VIII, and XI)

The Defendants also object to the Goodlings' fraud-based claims, asserting two separate bases for dismissal. First, the Defendants argue that as with the negligent misrepresentation claim, the fraud-based claims should be dismissed because they "are premised on a failure to warn theory," which Pennsylvania courts permit only if sounding in negligence.[111] Second, the Defendants argue that the Goodlings failed to plead their fraud-based claims "under the heightened standard of particularity required by Fed. R. Civ. P. 9(b)."[112]

As the Defendants note, the Goodlings "do not dispute that, to the extent that their fraud-based claims . . . are premised on a failure to warn theory, they should be dismissed."[113] Instead, the Goodlings argue that "[t]hese claims are not based solely on a concealment theory, but are also based on past, active, and ongoing misrepresentations to [Ms. Goodling] and/or her implanting physician."[114] The

---

[109] *Id*. (citing Doc. 13 ¶¶ 4–8, 21–23, 275–86).
[110] *See Drumheller*, 2021 WL 1853407, at *16–17 (allegations that plaintiff "sustained physical injuries" and "medically diagnosable" emotional distress "as a result of her pelvic mesh implantation" were sufficient to "state a claim for negligent infliction of emotional distress").
[111] Doc. 19 at 6 (citing *Drumheller*, 2021 WL 1853407, at *16).
[112] Doc. 17 at 18 (citing *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007)).
[113] Doc. 19 at 6.
[114] Doc. 18 at 12–13 (citing Doc. 13 ¶¶ 4–8, 21–23, 50–51, 59–64, 68–78, 82, 179–92, 224–74, 287–311).

Court finds these arguments unpersuasive. Although the Goodlings allege the Defendants "intentionally made false claims" and "actively misrepresented that the TVT [device] did not cause chronic injuries,"[115] their descriptions of these "misrepresentations" are wholly duplicative of the allegations underlying their failure to warn claims.[116] As Judge Kearney explained in *Drumheller*, district courts in this Circuit "routinely dismiss [as legally impermissible] fraud claims rooted in a failure to warn theory."[117]

Moreover, even if this Court accepted as true the Goodlings' argument that their fraud-based claims are factually and legally distinct from their failure to warn claims, they would still need to prove that the allegations underlying their fraud-based claims satisfy the heightened pleading standard of Rule 9(b). They have failed to do so.

Federal Rule of Civil Procedure 9(b) provides that when "alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud

---

[115] Doc. 13 ¶¶ 180, 182.

[116] *See*, *e.g.*, *id*., Count V (Common Law Fraud) ¶¶ 177 ("Defendants had a duty to disclose and/or not conceal the true and material risks" of their pelvic mesh products.), 178 (Although "it was known or knowable" to the Defendants that "their TVT [device] caused large numbers of complications that were not rare," the Defendants "continued to represent that their TVT [device] was safe and effective."), 180 (Defendants "made false claims regarding the true defective nature of the TVT [device] . . . ."), 188 (The Goodlings "and/or their implanting physicians justifiably relied on Defendants' misrepresentations and/or concealment of the above-referenced facts."), 189 ("[N]either [Ms. Goodling] nor her implanting physician was aware of [the concerns associated with the Defendants' pelvic mesh products], and had they been aware of said facts, they would not have acted as they did . . . .").

[117] 2021 WL 1853407, at *16 (citing *Runner*, 108 F. Supp. 3d at 268; *Kline v. Pfizer Inc.*, 2009 WL 32477, *4 (E.D. Pa. Jan. 6, 2009)).

or mistake."[118] The Third Circuit has held that "[t]o satisfy this standard, the plaintiff must plead or allege the date, time, and place of the alleged fraud or otherwise inject precision or some measure of substantiation into fraud allegations."[119]

Here, the Goodlings argue that "[t]he particularity requirement for this claim is relaxed since the requisite information was within [the] Defendants' exclusive knowledge and control, and the fraud occurred over an extended period of time, and consists of numerous acts."[120] But the Goodlings cite no legal authority for why these facts, if true, relax the heightened pleading standard for fraud outlined in Rule 9(b). Moreover, as the Defendants note, "this assertion cannot be reconciled with [the Goodlings'] own [Amended Complaint]."[121] The Goodlings allege the Defendants "knowingly made false claims about the safety and quality of the Defendants' [pelvic mesh] product in the documents and marketing material [the] Defendants provided to the FDA, physicians, and the general public."[122] Further, the Goodlings state that "[t]he substantial and particular fraud evidence that has been introduced in several pelvic mesh trials against [the] Defendants will be substantially similar, if not identical, to the evidence that will be introduced in this

[118] Fed. R. Civ. P. 9(b).
[119] *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007).
[120] Doc. 18 at 13.
[121] Doc. 19 at 7.
[122] Doc. 13 ¶ 73.b.

case."[123] Put simply, if the information needed to prove a fraud claim was "provided to the FDA, physicians, and the general public," and also produced "in several pelvic mesh trials," the Goodlings cannot claim that such information remains "within [the] Defendants' exclusive knowledge and control."[124]

Separately, the Goodlings argue that they "have pled their claims with particularity," in that they allege the following:

> Defendants misrepresented, omitted and downplayed the known risks, dangers, adverse events, contraindications, defects and disadvantages of the TVT [device]; willfully, intentionally, and maliciously misrepresented and concealed facts[;] and intentionally misrepresented, concealed and/or failed to disclose the true defective nature of the TVT [device] so that [Ms. Goodling] and her implanting physician would request and purchase the Defendants' TVT [device].[125]

But these allegations lack the specificity required by Rule 9(b). The Goodlings do not identify any specific statements or representations they consider fraudulent—that is, no particular marketing materials or documentation provided to Ms. Goodling or her implanting physician.[126] They also make no attempt to provide the dates or times of, or the places in which, the Defendants made these alleged

[123] Doc. 18 at 13–14.
[124] Doc. 13 ¶ 73.b; Doc. 18 at 13–14.
[125] Doc. 18 at 14 (citing Doc. 13 ¶¶ 59–62) (internal quotation marks omitted).
[126] *See* Doc. 13 ¶¶ 172 –92, 224–40, 287–311.

misrepresentations.[127] In short, the Goodlings failed to inject the precision required to properly allege fraud under Rule 9(b).[128]

For these reasons, the Goodlings' fraud-based claims (Counts V, VIII, and XI) are dismissed.

E. Breach of Warranty (Counts VI and VII)

The Defendants next argue that the Goodlings' breach of express and implied warranty claims are time-barred or otherwise deficient.[129] The Court agrees.

1. Statute of Limitations

Under Pennsylvania law, breach of warranty claims "must be commenced within four years after the cause of action accrues."[130] Pennsylvania courts have long recognized that "the tort discovery rule does not apply to breach of warranty actions,"[131] and, as such, the "cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge."[132] In cases such as this, "involving the implantation of a medical device, a breach of warranty cause of action accrues on the date the device is implanted."[133]

---

127 *Id*.
128 *Frederico*, 507 F.3d at 200.
129 Doc. 17 at 5–7.
130 13 Pa. C.S.A. § 2725(a).
131 *Northampton County Area Community College v. Dow Chemical, U.S.A.*, 566 A.2d 591, 599 (Pa. Super. 1989); *see also City of Philadelphia v. Lead Industries Association, Inc.*, 994 F. 2d 112, 121 n.7 (3d Cir. 1993) (same).
132 13 Pa. C.S.A. § 2725(b).
133 *Drumheller*, 2021 WL 18535407, at *13.

That said, the limitation period may be lengthened if the warranty "explicitly extends to future performance."[134] This exception unquestionably applies to *express* warranties; however, the Supreme Court of Pennsylvania has not squarely decided whether an *implied* warranty can be "explicitly" extended.

In *Cucchi v. Rollins Protective Services Co.*, a plurality of justices held that "[w]hile the term 'explicit' might seem to eliminate the possibility of *implied* prospective warranties, the better view is that warranties explicitly extending to future performance may be both express and implied by content and circumstances sufficiently specific as to unequivocally refer to future performance."[135] But subsequent Pennsylvania Supreme Court decisions call this ruling into question. In *Keblish v. Thomas Equipment, Ltd.*, the Court explained that "[b]ecause there was no clear majority supporting any given view, the precedential authority of *Cucchi* is limited to the facts of that case."[136] Further, in *Nationwide Insurance Co. v. General Motors Corp.*, the Court noted, albeit in dicta, that "the great weight of authority takes the position that an implied warranty, by nature, cannot 'explicitly' extend to future performance."[137] Pointing to this language, federal district courts in this Circuit have generally predicted that "if the [Supreme Court of

[134] 13 Pa. C.S.A. § 2725(b).
[135] 574 A.2d 565, 530 (Pa. 1990).
[136] 660 A.2d 38, 40 n.1 (Pa. 1995).
[137] 625 A.2d 1172, 1178 (Pa. 1993).

Pennsylvania] had occasion to rule on the issue," it would find "that implied warranties cannot be so extended."[138]

Here, Ms. Goodling alleges that she was implanted with the TVT device on December 5, 2011.[139] As such, the limitation period for her breach of warranty claims concluded on December 5, 2015—more than six years before she commenced this lawsuit.[140]

The Goodlings contend that they properly allege that the Defendants' warranties extend to future performance.[141] Specifically, they highlight the following allegations:

- "Defendants warranted that the TVT [device] will *permanently* cure or alleviate" Ms. Goodling's stress urinary incontinence" and *would not need to be removed*."[142]
- "Defendants warranted that their TVT [device] is a *permanent implant*, i.e., it is safe and effective and will cure or alleviate" Ms. Goodling's stress urinary incontinence "*for her entire life*."[143]
- "Defendants made several express warranties, including but not limited to: . . . (2) the TVT [device] does not contract or shrink, or otherwise deform; [and] (3) the TVT [device] does not degrade."[144]

---

[138] *McPhee v. DePuy Orthopedics, Inc.*, 989 F. Supp. 2d 451, 462–63 (W.D. Pa. 2012); *see also Drumheller*, 2021 WL 18535407, at *14 (holding that "an implied warranty cannot be 'explicitly extended to future performance'").
[139] Doc. 13 ¶ 2.
[140] *See* Doc. 1 (filed on January 14, 2021).
[141] Doc. 18 at 4–5.
[142] Doc. 13 ¶ 197 (emphasis added).
[143] *Id*. (emphasis added).
[144] *Id*. ¶ 207.

Consistent with the other district courts of this Circuit, this Court finds that an implied warranty cannot be "explicitly extend[ed] to future performance."[145] Therefore, the allegations that the warranties extended to future performance have no bearing on the limitation period for the Goodlings' implied warranty claim. Count VII is therefore dismissed with prejudice.

However, for the express warranty claim, the Goodlings' allegations are sufficient to extend the limitation period. By purportedly describing the TVT device as a "permanent implant" that will "permanently cure or alleviate" Ms. Goodling's stress urinary incontinence,[146] and also representing that the mesh product would not shrink, deform, or degrade,[147] the Defendants effectively "assur[ed] the product's performance over time."[148] At this stage, that is sufficient to establish that the express warranties "explicitly extend[] to future performance."[149]

2. Pleading Requirements

Separately, the Defendants argue that the breach of express warranty claim should be dismissed because the Goodlings "do not plead any specific affirmation of fact or promise made by [the] Defendants related to [the pelvic mesh product]

---

145 13 Pa. C.S.A. § 2725(b).
146 Doc. 13 ¶ 197.
147 *Id*. ¶ 207.
148 *Drumheller*, 2021 WL 18535407, at *14.
149 13 Pa. C.S.A. § 2725(b); *see also Drumheller*, 2021 WL 18535407, at *14 (finding it "plausible [that] the [Defendants' alleged] representation about the continued safety and efficacy of the permanent implant's performance extended to future performance").

that was breached."[150] To prevail on a breach of express warranty claim, a plaintiff must establish that the defendants made some form of promise or affirmative statement that the defendants breached or failed to meet and that the breach was the proximate cause of the specific damages sustained.[151] Under Pennsylvania law, an express warranty is created by "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain," or "[a]ny description of the goods" or "sample or model" that is made "part of the basis of the bargain."[152] Notably, "[i]n breach of express warranty cases, courts in our Circuit applying Pennsylvania law generally require a plaintiff to identify a specific affirmative statement to withstand a motion to dismiss."[153]

Here, the Goodlings do not identify the specific warranties on which Ms. Goodling allegedly relied. The Amended Complaint contains general descriptions of purported warranties—i.e., "Defendants warranted that their [pelvic mesh] product will permanently cure or alleviate" Ms. Goodling's stress urinary

---

150 Doc. 17 at 6.

151 *Samuel-Bassett v. Kia Motors America, Inc.*, 34 A.3d 1, 35 (Pa. 2011).

152 13 Pa. C.S.A. § 2313(a).

153 *Drumheller*, 2021 WL 18535407, at *14; *see also Soutner v. Covidien, LP*, 2019 WL 3801438, at *9 (M.D. Pa. Aug. 13, 2019) (Kane, J.) ("Without additional allegations detailing the explicit warranties for future performance of Defendant's mesh, the Court will not accept as true Plaintiff's assertion that Defendant's mesh contained any express warranty for future performance."); *Runner*, 108 F. Supp. 3d at 266–67 (dismissing breach of express warranty claims because plaintiff "failed to identify any affirmative statements by either defendant"); *McPhee*, 989 F. Supp. 2d at 466 ("Because Plaintiff cannot allege that any particular affirmation or fact or promise became 'part of the basis of the bargain' without alleging an affirmation of fact or promise, . . . Plaintiffs' complaint fails to allege facts sufficient to demonstrate a plausible claim for breach of express warranties under Pennsylvania law.").

incontinence, is a "permanent implant," "does not shrink or contract," and "does not degrade"[154]—but it provides no information on who made these statements, to whom they were made, when they were made, or how Ms. Goodling became aware of them. The Goodlings separately allege that the Defendants "specifically warranted to [Ms. Goodling] and her implanting physician through advertisements and marketing materials that the TVT [device] was 'safe and effective' and 'safer and more effective than other alternative procedures and devices.'"[155] But again, the Goodlings do not allege the specific materials containing these warranties and provide no information on how Ms. Goodling was exposed to these materials. Further, it is unclear whether the express warranties that tolled the statute of limitations—that is, the representations explicitly extending the warranties to future performance—were included in these same advertisements and marketing materials, or whether these alleged warranties were issued in some other fashion.

As noted, in *Drumheller*, Judge Kearney confronted a nearly identical complaint brought against the same defendants as in this case, alleging harm caused by the same product.[156] There, the plaintiff alleged breach of express warranty based on the exact warranties at issue here—indeed, the allegations appear to be copied verbatim:

> Ms. Drumheller alleges [the Defendants] generally stated the pelvic mesh product is 'safe and effective.' . . . Ms.

[154] Doc. 13 ¶¶ 197, 204.
[155] *Id.* ¶ 208.
[156] 2021 WL 1853407.

> Drumheller does not provide the specific warranties on which she allegedly relied. She instead paraphrases several alleged express warranties, alleging [the Defendants] warranted the product: 'does not contract or shrink, 'does not degrade,' and may 'only cause transient or temporal injuries.' She further alleges [the Defendants] warranted the pelvic mesh product will 'permanently cure or alleviate' her stress urinary incontinence and would need to be partially removed.[157]

Noting that the plaintiff "does not allege the specific materials containing these warranties, nor does she allege how she became aware of these materials," Judge Kearney found these allegations "insufficient to plead [the Defendants] made express warranties which became the basis of the bargain between the parties."[158]

This Court finds Judge Kearney's assessment of these allegations and this claim persuasive. Absent allegations identifying specific affirmative statements that Ms. Goodling relied on, the breach of express warranty claim cannot proceed. Count VI is therefore dismissed.

F. Other Claims

1. Unjust Enrichment (Count XII)

The Defendants ask the Court to dismiss the Goodlings' unjust enrichment claim because the Goodlings "merely allege their 'dissatisfaction with the product,' which is insufficient to state a claim for unjust enrichment."[159] The Court agrees.

---

[157] *Id*. at *15.
[158] *Id*.
[159] Doc. 17 at 19 (quoting *Drumheller*, 2021 WL 1853407, at *17).

In Pennsylvania, unjust enrichment claims fall into two categories: (1) "a quasi-contract theory of liability, in which case the unjust enrichment claim is pled in the alternative to a breach of contract"; and (2) "a theory based on underlying tortious conduct, in which case the unjust enrichment claim is a companion claim to the underlying tort."[160] Under the second theory, "the success of the unjust enrichment claim is dependent on the success of its predicate tort."[161] Moreover, "[i]n products liability cases, courts in this Circuit applying Pennsylvania law dismiss unjust enrichment claims where the plaintiff received and used the product at issue."[162]

Here, the Goodlings do not allege that Ms. Goodling paid for but never received the product at issue; rather, they allege her dissatisfaction with the product. That is insufficient to sustain a claim for unjust enrichment.[163] Therefore, Count XII is dismissed.

---

[160] *Silva v. Rite Aid Corporation*, 416 F. Supp. 3d 394, 403–04 (M.D. Pa. 2019) (Connor, J.) (citing *Khawaja v. RE/MAX Cent.*, 151 A.3d 626, 633 (Pa. Super. 2016); *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 936 (3d. Cir. 1999)).

[161] *Id*. (citing *Steamfitters*, 171 F.3d at 937).

[162] *Drumheller*, 2021 WL 1853407, at *17 (citing *Mazur v. Milo's Kitchen, LLC*, 2013 WL 3245203, at *10 (W.D. Pa. June 25, 2013); *Tatum v. Takeda Pharmaceuticals North America, Inc.*, 2012 WL 5182895, at *4–5 (E.D. Pa. Oct. 19, 2012)).

[163] *See Drumheller*, 2021 WL 1853407, at *18 (plaintiff "does not state a claim for unjust enrichment" where she "does not allege she paid for, but did not receive the product at issue"); *Tatum*, 2012 WL 5182895, at *5 (finding "[t]his is not a case in which a claim for unjust enrichment is appropriate" because "there is no allegation that defendants refused to provide a service or goods after [the plaintiff] provided defendants with a benefit").

2. Loss of Consortium (Count XIII)

The Defendants argue that the Goodlings' loss of consortium claim should be dismissed because it is "derivative of their underlying claims."[164] The Goodlings do not dispute that this claim is "derivative in nature."[165] Accordingly, the parties agree that if the Goodlings' "underlying claims [are] dismissed, their loss of consortium [claim] . . . must also be dismissed;"[166] however, if "any of [the Goodlings'] other claims remain pending," the derivative loss of consortium claim should likewise proceed.[167] Because the Court declines to dismiss the Goodlings' design defect and failure to warn claims (Counts I–II, IV) as well as their claim for negligent infliction of emotional distress (Count X), the loss of consortium claim predicated on these counts remains viable. The Defendants' motion to dismiss Count XIII is therefore denied.

3. Punitive Damages (Count XIV)

Finally, the Defendants correctly state that "punitive damages is not recognized as a separate cause of action, but instead, is a potential remedy for an underlying cause of action."[168] As such, this cause of action is dismissed with prejudice. To the extent the Goodlings seek punitive damages, they can do so only as a possible remedy for one of the separate causes of action.

---

[164] Doc. 17 at 19.
[165] *See* Doc. 18 at 15.
[166] Doc. 17 at 19.
[167] *See* Doc. 18 at 15.
[168] Doc. 17 at 20 (citing *Russell* 2020 WL 5993774, at *7).

IV. CONCLUSION

No matter how similar the suits, it is not advisable to simply copy pleadings used in separate complaints filed by separate plaintiffs. But that alone does not render a complaint invalid. Here, the allegations in the Amended Complaint properly state claims for design defect and failure to warn sounding in negligence and strict liability, as well as for negligent infliction of emotional distress and loss of consortium. As such, the Defendants' motion to dismiss Counts I, II, IV, X, and XIII is denied. However, the pleadings are insufficient to support the Goodlings' claims for manufacturing defect (Count III), fraud (Counts V, VIII, and XI), breach of warranty (Counts VI and VII), negligent misrepresentation (Count IX), unjust enrichment (Count XII), and punitive damages (Count XIV). Counts III, V, VI, VIII, and XI are dismissed without prejudice; if the Goodlings wish to plead over on these counts, they may do so. Counts VII, IX, XII, and XIV are dismissed with prejudice.

An appropriate Order follows.

BY THE COURT:

s/ Matthew W. Brann
Matthew W. Brann
Chief United States District Judge